

REMARKS/ARGUMENTS

Claims 2, 3, 5-9, and 13-15 remain in this application. Claims 2, 3 7 and 13 have been amended. Claims 4, and 10-12 have been canceled. Claims 16-18 have been added. The following issues are outstanding in the Office Action dated November 19, 2003:

1. Claims 2-9 were rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/05873 ("Lina et al.") in view of U.S. Patent Application No. 2003/0077311 A1 ("Vyakarnam et al.") and U.S. Patent No. 5,621,035 ("Lyles et al.");
2. Claims 10-12 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of Vyakarnam et al.;
3. Claims 13-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Lina et al. in view of U.S. Patent No. 5,615,794 ("Easton et al.").

Each of these will be addressed in turn.

1. Rejection of Claims 2-9 Under 35 U.S.C. 103(a)

In this rejection, the Examiner stated that Lina et al. disclose all features of the claimed invention including a porous foamed pad shaped to conform to a wound, an air-tight seal adhered to the skin and/or pad, and a negative pressure source in fluid communication with the pad. As to the biocompatibility of the pad, the Examiner states that since the pad can be placed on or within a wound cavity, the pad is inherently biocompatible. The Examiner notes that Lina et al. disclose the pad as being constructed from open cell polyurethane or polyether foam, both of which is biocompatible.

Vyakaarnam et al. was cited by the Examiner for bioabsorbable polymer foams to various areas of the body in order to promote tissue regeneration, and the use of a ceramic particle or fiber in combination with the foam in order to reinforce the foam such that the foam is strengthened so as to be structurally compatible with cancellous bone. Lyles et al. was cited for the disclosure of ultra-low density fused-fibrous ceramic.

The Examiner concluded it would have been obvious to provide the foam pad of Lina et al. with a ceramic in order to strengthen the foam as taught by Vyakarnam et al. The Examiner also concluded it would have been obvious to substitute the ceramic of Vyakarnam et al. for the ultra-low density fused-fibrous ceramic disclosed in Lyles et al. since Lyles et al. disclose that the ultra-low density fused-fibrous ceramic have additional desired properties such as high tensile strength, dimensional stability, low thermal conductivity, etc.

Claim 2 has been amended. Support for the amendment can be found at least on page 5, lines 8-11; page 6, lines 3-16; page 10, line 11—page 3, line 2. In particular, claim 2 is directed towards a pad having an ultra-low density fused fibrous ceramic removably attached to the

wound-contacting surface of the pad. The ceramic is adapted to act as a scaffold to facilitate cellular growth therethrough (thus remaining in the wound) and to be separated from the pad. Claim 4 has been canceled.

As identified by the Examiner, Lina et al. fails to teach such a biocompatible wound dressing. Likewise, Vyakarnam et al. fail to teach such a two-tiered biocompatible wound dressing that allows removal of one tier (the pad) while encouraging cellular growth in the other (the ceramic) and providing a scaffold for cellular growth therein. Particularly, Vyakarnam et al. teach reinforcing the foam to strengthen the foam for structural compatibility with cancellous bone (para. 0034).

This is an important difference. The ceramic of the invention of claim 2 can be used by the regrowing tissue in the wound as a template or scaffold for vascularized regeneration of the tissue as facilitated and encouraged by negative pressure. See p. 5, ll. 8-11 of the specification for support. Indeed, the invention of claim 2 does not benefit from any strengthening properties advocated by Vyakarnam et al. and identified by the Examiner, inasmuch as the removable connection of the ceramic and pad is adapted to facilitate a *permanent* template within the wound, not as a structural enhancement.

Lyles et al. fail to teach such a two-tiered biocompatible wound dressing as well. Rather, Lyles et al. teach a ultra-low density fused-fibrous ceramic having high tensile strength, dimensional stability, etc. *for strengthening the foam*(as identified by the Examiner), *not* as a removable template or scaffold in a two-tiered dressing adapted to remain in the wound and support vascularized tissue growth therethrough.

Clearly, none of these references, alone or in combination, teach, disclose or otherwise one of skill in the art to make a two-tiered wound dressing that has one tier adapted to be removed from the other, such that the remaining tier on the wound *facilitates cellular growth through the ceramic*. This is inherently so, inasmuch as negative pressure in combination with any of the devices disclosed in Vyakarnam et al., Lina et al. or Lyles et al. alone or in combination would inherently damage the wound when the dressing is removed because of several reasons: 1) there is no design of the cited references for removal of the dressing from the wound; 2) there is no indication for removal of the dressing(s) *after* cellular growth has invaded the dressing; and 3) there is no scaffolding for supporting the cellular growth in the dressing in any of the cited references. Or, and very importantly, the structural-enhancing properties of the dressing as combined by the Examiner and stated in the Office Action of June 2, 2004 would be defeated upon removal of the very component used to strengthen the dressing (while damaging the wound).

Claims 3, 5 and 6 are allowable for the same reasons.

Claim 7 has been amended to more accurately claim the invention to which Applicants are entitled. No new matter has been added. Support for this amendment can be found in the specification at least on page 10, lines 1-20. For the same reasons as set forth with respect to claim 2, above, claim 7 and dependent claims 8-9 are allowable over the art made of record, inasmuch as none of the references, alone or in combination, teach, suggest or otherwise motivate one of skill in the art to create a biocompatible wound dressing including a non-bioabsorbable substrate and an ultra-low density fused-fibrous ceramic, with the ultra-low density fused-fibrous ceramic being adapted to be absorbed or included by the wound and the

ceramic being removably connected to the wound-contacting surface of the pad and allow cellular growth therein.

Accordingly, claims 7-9 are submitted to be in condition for allowance.

2. Rejection of Claims 10-12 Under 35 U.S.C. 103(a)

Claims 10-12 have been canceled from the application.

3. Rejection of Claims 13-15 Under 35 U.S.C. 103(a)

For this rejection, the Examiner applied Lina et al. for disclosing all the features of the claim except that the pad comprises a cell-growth enhancing matrix. Easton et al. was cited for disclosing a wound dressing comprising the biodegradable protein collagen. The Examiner concluded it would have been obvious to one of skill in the art to add the dressing of Easton et al. to the pad of Lina et al. in order to enhance or improve cellular growth at the wound site.

Claim 13 has been amended. Support for the amendment can be found in the specification at least on page 5, lines 19-21; and page 9, lines 4-20. No new matter has been added.

Important distinctions exist in the inventions of Lina et al. and Easton et al. and the invention of claim 13 that would discourage one of skill from combining the inventions therein to achieve the present invention of claim 13. These are described below in more detail.

- A. Lina et al. is directed to a *reticulated biocompatible* pad that is *inherently not bioabsorbable*.**

Lina et al. teach “[a] *high degree of reticulation* in the polymer foam is desirable to achieve good permeability when the foam is under suction. Foams having at least 90% and especially at least 95% of interconnecting cells are preferred.” (Emphasis added); page 8, lines 21-23. This is necessary to allow *fluid* permeation from the wound site to the negative pressure source of Lina et al. See page 8, line 10.

Importantly, Lina et al. disclose a polyurethane film with a removable backing sheet (polythene), which although is biocompatible, is *not* adapted to be absorbed by or included into the wound. Indeed, these materials, if left in a wound, result in a stiff, fibrous encapsulating bio-response, such as scarring.

B. The wound dressing formed according to the disclosure of Easton et al. is *inherently non-reticulated*.

The formation of the complexes of Easton et al. inherently *teaches away* from the reticulated foam of Lina et al. Specifically, Easton et al. teach four different formations for its complex: 1) formation by precipitate from an aqueous medium; 2) organic solvent washing then dried under vacuum; 3) blast-freezing with organic solvent; and 4) (and the preferable embodiment) by freeze-drying. See col. 3, l. 46-col. 4, l. 6. Each of these is completely different and counter-purpose from Lina et al. and will be addressed below.

First, the formation of the complex by formation as a precipitate from an aqueous medium (col. 3, lines 47-50) leads to the formation of a *film*. This is specifically identified in Easton et al.: “The complexes can be dried under atmospheric conditions, and, prior to drying, may be spread to form films.” Col. 3, lines 46-49. The films of

Easton et al. inherently are not matrices. Rather, the precipitate (film) is a liquid-impermeable, non-bulky layer of material that cannot be utilized as a scaffold or template for tissue formation. Oppositely, the objective of growth-enhancing matrices is to encourage the development of tissue bulk. Thin films do not, by their nature, provide that bulk. Films can be stacked in multiple layers (to create bulk), but this will even further reduce the liquid permeability, if any, of the stacked material.

Second, the organic solvent washing formation of complexes taught by Easton et al. “yields a very fibrous material”. *See* col. 3, lines 49-54. This fine, fibrous material, although possibly bulky, inherently collapses when subjected to negative or positive pressure due to lack of structural integrity. Thus, the fibrous material cannot be used as a substitute for a matrix of the present invention, inasmuch as negative pressure applied thereto collapses the pores of the fibrous material and prevents or impairs cellular growth therein. Inherently, this is non-reticulated, and is opposite to the teachings of Lina et al. (and the present invention).

Third, blast freezing with the replacement of frozen water with a suitable organic solvent fails to solve the problem described above. *See* col. 3, lines, 55-57. Although “sponge-like” structures are formed, which will have more structural integrity than the fibrous material of the second embodiment of Easton et al., this sponge-like structure is inherently non-reticulated (and thus, lacking a high degree of interconnecting cells for fluid permeability) due to the formation method

This will simply not work with V.A.C.® therapy, which requires “sufficiently numerous open cells so that drainage...may continue unimpaired”. P. 5, ll. 6-7 of the

present invention specification. The lack of the interconnecting cells and poor reticulation as taught by Easton et al. would prevent fluid permeability and destroy the purpose of V.A.C. therapy, especially when used in conjunction with the present invention (which requires high reticulation). *See* p. 8, l. 17 – p. 9, l. 9 of the specification.

Likewise, the fourth disclosed embodiment (and preferred), is a modification of the third embodiment above, inasmuch as water is removed from the aqueous medium by freeze-drying. Col. 3, lines 58-65. This concept is inherently non-reticulated as well, inasmuch as the ice crystals formed by the freeze-drying process will create isolated cells at best, therefore discouraging liquid permeability of the complex.

This is even recognized by Easton et al., which is adapted to allow the penetration of fibroblasts (but not specifically vascularization) into the complex and, only when desired, high *vapor* permeability through the specific *increase* in pore sizes. Col. 4, ll. 3-6. Accordingly, the disclosed embodiments of Easton et al. all are inherently *liquid impermeable*.

Indeed, not only would liquid permeability be substantially impaired or impossible utilizing any of these methods disclosed in Easton et al., mainly because *none of these embodiments disclose reticulated, liquid-permeable dressings capable of withstanding negative pressure that allow tissue growth therein*, but the pore size disclosure for mere *vapor* permeability¹ is specifically described as higher than the

¹ Pore size for vapor permeability is inherently smaller than pore size for liquid permeability.

preferable range.² As a result, Easton et al. teaches completely away from Lina et al., which requires a high degree of liquid permeability from the wound when the dressing is under negative pressure.

Given the counter-purposes and cross-teachings of Easton et al. and Lina et al., one of skill in the art would not combine any part of the invention of Easton et al. with Lina et al. to achieve the invention of claim 13. Accordingly, claim 13 and dependent claims 14-17 are submitted to be in condition for allowance.

4. Claims and 18

Claim 18 is submitted to be allowable over the cited art of record for the reasons described herein above.

² Greater than 20 microns, more preferably greater than 50 microns to allow fibroblast penetration, and 100 microns for (mere) moisture vapor permeability

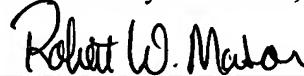
SUMMARY

Believing it has addressed all matters raised by the Examiner's June 2, 2004 Final Office Action, Applicants respectfully request timely action on the merits. No fees are believed to be required for the amendment. Nevertheless, the Commissioner is permitted to deduct or credit any fees that may be required from Kinetic Concept Inc. Deposit Account No. 500-326.

If upon consideration of the above, the Examiner should feel that outstanding issues remain in the present application that could be resolved, the Examiner is invited to contact the undersigned at the telephone number indicated to discuss resolution of such issues.

Applicants respectfully request favorable consideration.

Respectfully submitted,



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